

To: General Practitioners
PCT Immunisation co-ordinators

28 July 2010

Copy: Consultants in Communicable Disease Control
Royal College of Paediatrics and Child Health
Royal College of Physicians
Faculty of Public Health
Accident and Emergency Departments
All Pharmacists

Gateway Reference Number: 14613

Dear Colleague,

Risk of febrile convulsions in children aged under five years and seasonal influenza vaccines marketed by Pfizer Vaccines (Enzira® and CSL Biotherapies generic influenza vaccine)

I am writing to alert you to a possible increased risk of febrile convulsions in children under five years of age associated with the use of influenza vaccine marketed by Pfizer Vaccines for the 2010/11 influenza season (Enzira® and CSL Biotherapies generic influenza vaccine).¹

Epidemiological information from Australia^{2,3} indicates that there has been a higher than expected increase in febrile convulsions in children related to the use of Fluvax (manufactured by CSL). This is the same product that will be marketed in the UK by Pfizer as Enzira® and generic influenza vaccine⁴ for the 2010/11 influenza vaccination season. Evidence from Australia suggests a rate of febrile convulsions of about one per 100 for children who were vaccinated with Fluvax. This increased risk appears to be a product specific reaction and evidence from Australia of vaccination with other products has so far not indicated a similar level of risk.

¹ This alert does **not** apply to the generic influenza vaccine marketed by Sanofi Pasteur MSD, Inactivated Influenza Vaccine (Split Virion) BP.

² [http://www.health.gov.au/internet/main/publishing.nsf/Content/C8D6BEB67768E80ACA257735002424BF/\\$File/dept%20010610.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/C8D6BEB67768E80ACA257735002424BF/$File/dept%20010610.pdf)

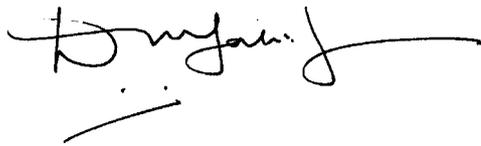
³ <http://www.tga.gov.au/alerts/medicines/flu vaccine-report100702.htm>

⁴ Marketing authorisation PL 22236/0001 held by CSL Biotherapies GmbH covers: Enzira® Suspension for injection, pre-filled syringe; and, Influenza vaccine (split virion, inactivated) Ph. Eur. This generic vaccine may also be identified as CSL Biotherapies generic flu vaccine.

It is important that children over six months of age who are in clinical risk groups receive influenza vaccination. Given the availability of other influenza vaccine products, you should avoid offering Enzira® or CSL Biotherapies generic influenza vaccine marketed by Pfizer to children aged under five years. Please check which manufacturer's products you have ordered (including the possibility that you have ordered CSL Biotherapies generic influenza vaccine) and ensure that you have stocks of alternative influenza vaccines to give to such children in the 2010/11 influenza vaccination programme.

There is currently no evidence to indicate that other influenza vaccines may be associated with this level of risk in children. Nonetheless, the Medicines and Healthcare products Regulatory Agency (MHRA) intends to closely monitor this and will issue further information in advance of this year's immunisation programme.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D M Salisbury', with a long horizontal flourish extending to the right.

Professor D M SALISBURY CB
FRCP FRCPCH FFPH
Director of Immunisation